

original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(9) *Representative sampling of advertisements* means typical advertising material (excluding labeling as determined in §202.1(1) (1) and (2)) that gives a balanced picture of the promotional claims used for the drug, e.g., if more than one medical journal advertisement is used but the promotional content is essentially identical, only one need be submitted.

(10) *Representative sampling of any other labeling* means typical labeling material (excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug, e.g., if more than one brochure is used but the promotional content is essentially identical, only one need be submitted.

(11) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(b) The definitions and interpretations of terms in sections 201, 502(e), and 510 of the act apply to the use of terms in this part.

[45 FR 38043, June 6, 1980, as amended at 55 FR 11576, Mar. 29, 1990; 66 FR 59156, Nov. 27, 2001]

#### **§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.**

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM-375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, on Form FDA-2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

(b) [Reserved]

(c) Owners and operators of establishments engaged in manufacture or processing of medical devices shall register and list their products with the Center for Devices and Radiological Health, FDA, on Form FDA-2891 (Initial Registration of Device Establishments), FDA-2891a (Registration of Device Establishment), and FDA-2892 (Medical Device Listing), in accordance with part 807.

(d) Owners and operators of establishments engaged in the manufacture or processing at the same establishment of both drug products and medical devices shall (1) register with the Records Repository Team (HFD-143), Center for Drug Evaluation and Research, FDA, and list their drug products in accordance with this part, and (2) register with the Center for Devices and Radiological Health and list their medical devices in accordance with part 807.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 66 FR 59156, Nov. 27, 2001; 69 FR 48775, Aug. 11, 2004]

### **Subpart B—Exemptions**

#### **§ 207.10 Exemptions for establishments.**

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

(a) Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail. The supplying of prescription drugs by these pharmacies to a practitioner licensed to administer these drugs for his or her use in the course of professional practice or to other pharmacies to meet temporary

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inventory shortages are not acts that require pharmacies to register.

(b) Hospitals, clinics, and public health agencies that maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy or medicine and that regularly engage in dispensing prescription drugs, other than human blood or blood products, upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care.

(c) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture or process drugs solely for use in their professional practice.

(d) Persons who manufacture or process drugs not for sale but solely for use in research, teaching, or chemical analysis.

(e) Manufacturers of harmless inactive ingredients that are excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part.

(f) Persons who only manufacture the following:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds, and/or;

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(3) Persons who manufacture free-choice feeds, as defined in § 510.455 of this chapter, or medicated liquid feeds, as defined in § 558.5 of this chapter, where a medicated feed mill license is required are not exempt.

(g) Any manufacturer of a virus, serum, toxin, or analogous product intended for treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)), provided that this exemption from registration applies only to the manufacture or processing of that animal virus, serum, toxin, or analogous product.

(h) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

[45 FR 38043, June 6, 1980, as amended at 51 FR 7389, Mar. 3, 1986; 64 FR 63203, Nov. 19, 1999; 66 FR 59156, Nov. 27, 2001]

### Subpart C—Procedures for Domestic Drug Establishments

#### § 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart B of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register and submit a list of every drug in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Drug listing is not required for the manufacturing, preparation, propagation, compounding, or processing of an animal feed bearing or containing an animal drug (i.e., a Type B or Type C medicated feed), nor is drug listing required for establishments engaged in drug product salvaging. Drug products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce. No owner or operator may register an establishment if any part of the establishment is registered by any other owner or operator.

(b) Owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. A distributor who submits drug listing information shall include the registration number of the drug establishment that manufactured, prepared, propagated, compounded, or